HFD-613

NDA 17-576/S-045
NDA 17-716/S-045
NDA 18-127/S-033

AUG 10 1998

Bristol-Myers Squibb Company
Attention: Joseph A. Linkewich, Pham. D.
Director, Regulatory Affairs
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Linkewich:

Please refer to your supplemental new drug applications dated March 26, 1996, received April 1, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Ovcon 0.4/35 28 Day (NDA 17-716);
Ovcon-50 28 Day (NDA 17-576); and
Ovcon 0.4/35 21 Day (NDA 18-127)
(norethindrone and ethinyl estradiol) tablets.

We acknowledge receipt of your submission dated May 20, 1998. Your submission of May 20, 1998, constituted a full response to our November 10, 1997, action letter.

These supplemental new drug applications provide for the following changes to the Prescribing Package Insert:

PRECAUTIONS section

The addition of a ***Pediatric Use*** subsection which reads:

"Safety and efficacy of OVCON 35 and OVCON 50 have been established in women of reproductive age.Safety and efficacy are expected to be the same in postpubertal adolescents under the age of 16 years and in users ages 16 years and older.Use of this product before menarche is not indicted."

Additionally, the sponsor has replaced 'the statement "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION" with the wording "Rx only".

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert dated May 20, 1998). Accordingly, these supplemental applications are approved effective on the date of this letter.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that **you** submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Christina Kish, Project Manager, at (301)

Sincerely,

Marcellus 8/7/97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research